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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/432,523	11/03/1999	JOEL DONALD GRAY	100344-005-	1168

7590 07/06/2006

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EXAMINER

ISABELLA, DAVID J

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 07/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/432,523

Applicant(s)

GRAY ET AL.

Examiner

DAVID J. ISABELLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37, 39, 41, 43 and 45-54 is/are pending in the application.
- 4a) Of the above claim(s) 43 and 45-54 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 41 is/are allowed.
- 6) ☒ Claim(s) 37 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/7/02
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Status of the Claims

Currently claims 37,39,41 are pending for immediate consideration. Claims 1-36,42,44 have been cancelled and claims 43,45-54 have been withdrawn as being directed to a non-elected invention/species. This amendment as filed as a RCE on 4/10/2006.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 37,39 are rejected under 35 U.S.C. 102(b) as being anticipated by Malecki et al (5626607).

Malecki et al discloses a surgical clamp (600) comprising:

a malleable hollow shaft (681) including a distal end (682) and a proximal end (688);

a tissue engaging means (602) including first and second movable opposable jaws (620,622) mounted at the distal end (682) adapted to grasp, secure and occlude body tissue and conduits (see column 23, lines 15-25);

a handle assembly (604) including first and second movable arms (see handle embodiment in figures 3, 10A, 17 and 31A and column 22, lines 45+) mounted at the proximal end;

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a jaw actuating means (606) disposed within the hollow shaft (681) including a first end (618) operatively connected to the tissue clamp assembly and a second end (670) operatively connected to the handle assembly such that when the handle arms are moved from a first relative position to a second relative position, the first and second jaws of the tissue clamp assembly are moved between an open spaced apart position and a closed tissue gripping position or vice versa. Note figures 31A-C showing coupling means at each end that, in turn, allows separation of the jaw actuating means from the shaft member and the handle assembly.

Claim 34, see sockets in embodiments 31A and 31C.

Claims 35 and 36, see ball elements 456 and 448.

Claim 37 is essentially the same subject matter of claim 33 supra. The preamble of the claim is directed to "A disposable surgical device". The device of Malecki et al, while does not specifically disclose the concept of disposability, the device, is in fact, disposable as broadly claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 37,39 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGuire (3915169) in view of Malecki et al (5626607) and alternatively, Malecki, et al (5623307) in view of McGuire (3915169).

McGuire discloses a malleable hollow shaft (12) including a distal end (21) and a proximal end (14);

a tissue engaging means (602) including first and second movable opposable jaws (620,622) mounted at the distal end (682) adapted to grasp, secure and occlude body tissue and conduits (see column 23, lines 15-25);

a handle assembly (1) including first arms;

a jaw actuating means (8) disposed within the hollow shaft (12) including a first end operatively connected to the tissue clamp assembly and a second end (15) operatively connected to the handle assembly such that when the handle arm is moved from a first relative position to a second relative position, the jaws of the tissue clamp assembly are moved between an open spaced apart position and a position or vice versa. While McGuire is directed to a surgical knife, Malecki et al teaches that similar surgical tools may be equally employed as tissue clamps. To change the jaws arrangements of McGuire such that the tool may be employed to perform various other functions including that of a clamp would have been obvious from the teachings of Malecki,et al. The single arm assembly of McGuire could employ two arms actuation handle without departing from the scope of the invention thereof as such change would have been obvious to one with ordinary skill in the art based on design and/or

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engineering considerations of equivalent actuation systems known in the art, as shown, for example, by Malecki et al.

Alternatively, to employ a malleable shaft formed of materials which can be formed into various shapes without breaking or returning to its original shape would have been obvious from the teachings of McGuire. As such, the need for an additional positioner element would not be required by Malecki, et al.

Response to Arguments

Applicant's arguments filed 11/9/2005 have been fully considered but they are not persuasive. The amendment includes the language of "capable of being placed in different curvatures in the absence of the assistance of an additional member". It should be noted that the language "capable" does not positively preclude the use of an additional member. Moreover, as illustrated in figures 35 and 36, the device taken as a whole (ie combination of the elements 600 and 680) would result in the device as broadly claimed by applicant. In comparing figure 2 of applicant's device, it can be seen that the malleable shaft 114 is analogous to the same as illustrated by element 680 of Malecki et al.

With respect to the 35USC 103 rejection of Mulier et al in view of McGuire to the claims, applicant has not argued the outstanding rejection.

With respect to the 35USC 103 rejection of McGuire in view of Malecki et al and/or alternatively, Malecki et al in view of McGuire, examiner contends that one does

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not need to perceive element 680 as being an additional element but rather may look to the combination of elements 600 and 680 as a surgical device similarly illustrated in figure 2 of applicant's drawings which show separate elements 114 and 131.

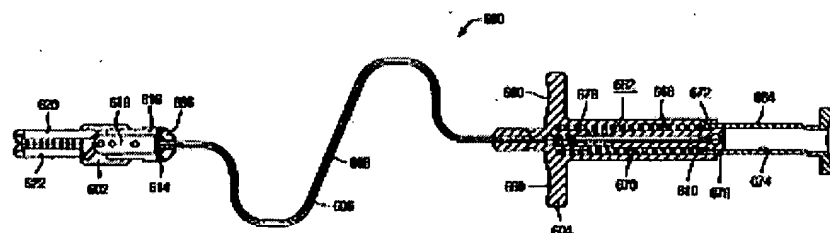


FIG. 35

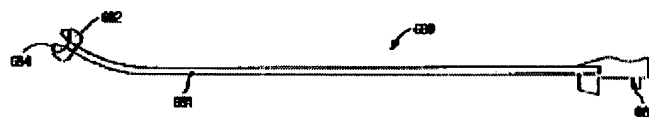


FIG. 36

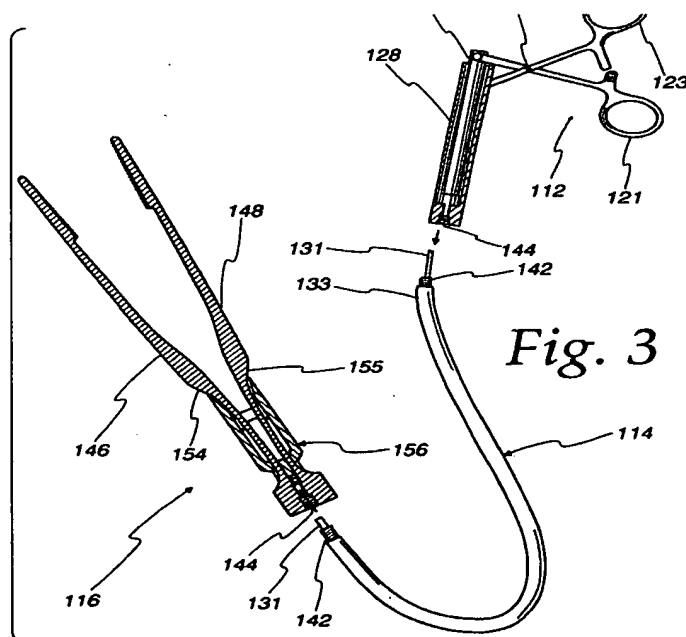


Fig. 3

Allowable Subject Matter

Claim 41 is allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J ISABELLA whose telephone number is 703-308-3060. The examiner can normally be reached on MONDAY-THURSDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID J ISABELLA
Primary Examiner
Art Unit 3738

DJI
6/25/2006